

What is claimed is:

1. A method for the detection and/or quantitation of nucleic acid in a sample, which comprises:

- a) mixing at least one random primer at least 4 nucleotides in length, having at least one detectable species with a sample nucleic acid,
- b) adding at least one ~~NTP~~ ^{nucleotide triphosphate} having at least one binding species and optionally at least one ~~NTP~~ ^{nucleotide triphosphate},
- c) adding at least one nucleic acid polymerase,
- d) incubating the mixture of step c), under conditions which allow said at least one nucleic acid polymerase to be active,
- e) contacting the mixture of step d) with at least one solid phase,
- f) detecting and/or quantitating the amount of nucleic acid in said sample by detecting and/or quantitating the amount of said at least one detectable species bound to said solid phase.

2. A method for the detection and/or quantitation of nucleic acid in a sample, which comprises:

- a) mixing at least one random primer at least 4 nucleotides in length, having at least one binding species with a sample nucleic acid,
- b) adding at least one ~~NTP~~ ^{nucleotide triphosphate} having at least one detectable species and optionally at least one ~~NTP~~ ^{nucleotide triphosphate},
- c) adding at least one nucleic acid polymerase,
- d) incubating the mixture of step c), under conditions which allow said at least one nucleic acid polymerase to be active,
- e) contacting the mixture of step d) with at least one solid phase,
- f) detecting and/or quantitating the amount of nucleic acid in said sample by detecting and/or quantitating the amount of said at least one detectable species bound to said solid phase.

3. A method for the detection and/or quantitation of nucleic acid in a sample, which comprises:

- a) mixing at least one random primer at least 4 nucleotides in length with a sample nucleic acid,
- b) adding at least one NTP having at least one binding species and optionally at least one NTP having at least one detectable species and optionally at least one NTP,
- c) adding at least one nucleic acid polymerase,
- d) incubating the mixture of step c), under conditions which allow said at least one nucleic acid polymerase to be active,
- e) contacting the mixture of step d) with at least one solid phase,

- f) detecting and/or quantitating the amount of nucleic acid in said sample by detecting and/or quantitating the amount of said at least one detectable species or the amount of said at least one binding species bound to said solid phase.

4. A method for the detection and/or quantitation of nucleic acid in a sample, which comprises:

- a) mixing at least one labeled random primer at least 4 nucleotides in length having at least one binding species and optionally at least one detectable species, with a sample nucleic acid
b) adding at least one nucleic acid ligase
c) adding at least one NTP
d) incubating the mixture of step c), under conditions which allow said at least one nucleic acid ligase to be active,
e) contacting the mixture of step d) with at least one solid phase,
f) detecting and/or quantitating the amount of nucleic acid in said sample by detecting and/or quantitating the amount of said at least one detectable species or the amount of said at least one binding species bound to said solid phase.

5. A method for the detection and/or quantitation of nucleic acid in a sample, which comprises:

- a) mixing at least one labeled random primer at least 4 nucleotides in length having at least one binding species and optionally at least one detectable species, with a sample nucleic acid
b) adding at least one nucleic acid ligase and at least one nucleic acid polymerase
c) adding at least one NTP
d) incubating the mixture of step c), under conditions which allow said at least one nucleic acid ligase and at least one nucleic acid polymerase to be active,
e) contacting the mixture of step d) with at least one solid phase,
f) detecting and/or quantitating the amount of nucleic acid in said sample by detecting and/or quantitating the amount of said at least one detectable species or the amount of said at least one binding species bound to said solid phase.

6. A method as in claim 1, ~~wherein said at least one binding species is selected from the group consisting of biotin, avidin, streptavidin, antibody, antigen, lectin, receptor, ligand, hormone, nucleic acid sequence, mimitope and nucleic acid base pairing polymer.~~

7. A method as in claim 1, ~~wherein said at least one detectable species is selected from the group consisting of biotin, avidin, streptavidin, antibody, antigen, lectin, receptor, ligand, hormone, nucleic acid sequence, mimitope, nucleic acid base pairing polymer, fluorescent molecule, electrochemiluminescent molecule, radioactive molecule, colored molecule, peroxidase, alkaline phosphatase and enzymes capable of producing a detectable species.~~

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Sub C1
8. A method as in claim 1, ~~wherein~~ wherein said at least one nucleic acid polymerase is selected from the group consisting of Taq DNA polymerase, T4 DNA polymerase, Klenow fragment (3'-5'), Pfu DNA polymerase, Exo- Pfu DNA polymerase, E.coli DNA polymerase I, Klenow fragment of DNA polymerase I, MMLV reverse transcriptase and AMV reverse transcriptase.

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9. A method as in claim 1, ~~wherein~~ wherein said at least one solid phase is selected from the group consisting of fiber, fibril, plastic surface, plastic bead, magnetic bead, plastic tube, gold surface, metal surface, metal bead and colloids.

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10. A method as in claim 1, ~~wherein~~ wherein said at least one ^{nucleotide triphosphate} ~~NTP~~ is selected from the group consisting of dATP, dGTP, dCTP, dUTP, dTTP, ATP, CTP, GTP, TTP, UTP inosineTP, propyne dCTP, propyne dUTP, 5-bromo dCTP, 5-iodo dUTP, 5-fluoro dUTP, O-6 methyl dGTP, 7-deaza dGTP, N-6 methyl-2'-dATP, biotin-dATP, biotin-dCTP, biotin-dUTP, digoxigenin dUTP, digoxigenin UTP and biotin ddUTP.

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11. A method as in claim 1, ~~wherein~~ wherein said at least one random primer is 4-70 nucleotides.

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Sub D4
12. A method as in claim 1, ~~wherein~~ wherein said conditions comprise a solution with a pH between 5.5 and 9.5, a ^{nucleotide triphosphate} ~~NTP~~ concentration between 1pM and 10mM, a Mg2+ concentration between 0.05mM and 500mM, and a reducing agent concentration between 0 and 500mM, where the sum of the molarities is between 1mM and 500mM.

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Sub C2
13. A method as in claim 4 ~~or 5~~ wherein said at least one ligase is selected from then group consisting of Pfu DNA ligase, T4 DNA ligase, Taq DNA ligase, T4 RNA ligase, and E.coli DNA ligase.

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Sub D4
14. A method as in claim 1 wherein said random primer is from 4 to 20 nucleotides in length.

15. A method as in claim 14 wherein said at least one ^{detectable} ~~label~~ is selected from the group consisting of biotin, nucleic acid sequence, nucleic acid base pairing linear polymer, fluorescent molecule, electrochemiluminescent molecule, radioactive molecule, peroxidase and alkaline phosphatase.

16. A method as in claim 14 wherein said at least one binding species is selected from the group consisting of biotin, antigen, lectin, ligand, hormone, nucleic acid sequence, mimitope and nucleic acid base pairing linear polymer.

17. A method as in claim 14 wherein said at least one nucleic acid polymerase is selected from the group consisting of Taq DNA polymerase, Klenow fragment (3'-5') E.coli DNA polymerase I and Klenow fragment of DNA polymerase I.

18. A method as in claim 14 wherein said at least one solid phase is selected from the group consisting of magnetic bead, plastic plate and polymer bead.

19. A method as in claim 14 wherein said at least one ~~NTP~~ ^{nucleotide triphosphate} is selected from the group consisting of dATP, dGTP, dCTP, dUTP, dTTP, 7-deaza dGTP, biotin-dATP, biotin-dCTP, biotin-dUTP, digoxigenin dUTP, digoxigenin UTP and biotin ddUTP.

20. A method as in claim 14 wherein said random primer is 6-10 nucleotides in length.

21. A method as in claim 14 wherein said conditions comprise those optimal for Klenow fragment of DNA polymerase I to synthesize DNA.

22. A method as in claim 20 wherein said ~~NTP~~ ^{nucleotide triphosphate} is a dNTP.

23. A method for the detection and/or quantitation of nucleic acid in a sample, which comprises:

- a) mixing at least one random primer at least 4 nucleotides in length having at least one detectable species, with a sample nucleic acid,
- b) adding at least one ~~NTP~~ ^{nucleotide triphosphate} having at least one binding species and optionally at least one ~~NTP~~ ^{nucleotide triphosphate},
- c) adding at least one nucleic acid polymerase,
- d) incubating the mixture of step c), under conditions which allow said at least one nucleic acid polymerase to be active,
- e) quantitating the amount of nucleic acid in said sample by detecting and/or quantitating the amount of said at least one detectable species or the amount of said at least one binding species.

24. A method for the detection and/or quantitation of nucleic acid in a sample, which comprises:

- a) mixing at least one random primer at least 4 nucleotides in length, having at least one binding species, with a sample nucleic acid,
- b) adding at least one ~~NTP~~ ^{nucleotide triphosphate} having at least one detectable species and optionally at least one ~~NTP~~ ^{nucleotide triphosphate},
- c) adding at least one nucleic acid polymerase,
- d) incubating the mixture of step c), under conditions which allow said at least one nucleic acid polymerase to be active,
- e) quantitating the amount of nucleic acid in said sample by detecting and/or quantitating the amount of said at least one detectable species or the amount of said at least one binding species.

25. A method for the detection and/or quantitation of nucleic acid in a sample, which comprises:

- a) mixing at least one random primer at least 4 nucleotides in length with a sample nucleic acid,
- b) adding at least one NTP having at least one binding moiety and optionally at least one NTP having at least one label and optionally at least one NTP,
- c) adding at least one nucleic acid polymerase,
- d) incubating the mixture of step c), under conditions which allow said at least one nucleic acid polymerase to be active,
- e) quantitating the amount of nucleic acid in said sample by detecting and/or quantitating the amount of said at least one label or the amount of said at least one binding moiety.

26. A method for the detection and/or quantitation of nucleic acid in a sample, which comprises:

- a) mixing at least one labeled random primer at least 4 nucleotides in length having at least one binding species and optionally at least one detectable species, with a sample nucleic acid,
- b) adding at least one nucleic acid ligase,
- c) adding at least one NTP,
- d) incubating the mixture of step b), under conditions which allow said at least one nucleic acid ligase to be active,
- e) quantitating the amount of nucleic acid in said sample by detecting and/or quantitating the amount of said at least one detectable species or the amount of said at least one binding species.

27. A method for the detection and/or quantitation of nucleic acid in a sample, which comprises:

- a) mixing at least one labeled random primer at least 4 nucleotides in length having at least one binding species and optionally at least one detectable species, with a sample nucleic acid,
- b) adding at least one nucleic acid ligase and at least one nucleic acid polymerase,
- c) adding at least one NTP,
- d) incubating the mixture of step b), under conditions which allow said at least one nucleic acid ligase and at least one nucleic acid polymerase to be active,
- e) quantitating the amount of nucleic acid in said sample by detecting and/or quantitating the amount of said at least one detectable species or the amount of said at least one binding species.

28. A method as in claim 23, ~~wherein said at least one detectable species is selected from the group consisting of biotin, avidin, streptavidin, antibody, antigen, lectin, receptor, ligand, hormone, nucleic acid sequence, mimitope, nucleic acid base pairing linear polymer, fluorescent molecule, electrochemiluminescent molecule, radioactive molecule, colored molecule, peroxidase, alkaline phosphatase and enzymes capable of producing a detectable species.~~

29. A method as in claim 23, ~~wherein said at least one nucleic acid polymerase is selected from the group consisting of Taq DNA polymerase, T4 DNA polymerase, Klenow fragment (3'-5'), Pfu DNA polymerase, Exo- Pfu DNA polymerase, E.coli DNA polymerase I, Klenow fragment of DNA polymerase I, MMLV reverse transcriptase and AMV reverse transcriptase.~~

30. A method as in claim 23, ~~wherein said at least one NTP is selected from the group consisting of dATP, dGTP, dCTP, dUTP, dTTP, ATP, CTP, GTP, TTP, UTP inosineTP, propyne dCTP, propyne dUTP, 5-bromo dCTP, 5-iodo dUTP, 5-fluoro dUTP, O-6 methyl dGTP, 7-deaza dGTP, N-6 methyl-2'-dATP, biotin-dATP, biotin-dCTP, biotin-dUTP, digoxigenin dUTP, digoxigenin UTP and biotin ddUTP.~~

31. A method as in claim 23, ~~wherein said at least one random primer is 4-70 nucleotides.~~

32. A method as in claim 23, ~~wherein said conditions comprise a solution with a pH between 5.5 and 9.5, a NTP concentration between 1pM and 10mM, a Mg2+ concentration between 0.05mM and 500mM, and a reducing agent concentration between 0 and 500mM, where the sum of the molarities is between 1mM and 500mM.~~

33. A method as in claim 26 ~~or 27~~ wherein said at least one ligase is selected from then group consisting of Pfu DNA ligase, T4 DNA ligase, Taq DNA ligase, T4 RNA ligase, and E.coli DNA ligase.

34. A kit comprising

- a vial containing at least one random primer at least 4 nucleotides in length having at least one detectable species, and containing at least one ~~NTP~~ ^{nucleotide triphosphate} having at least one binding species and optionally at least one ~~NTP~~ ^{nucleotide triphosphate}
- a vial containing at least one nucleic acid polymerase, and
- a vial containing at least one solid phase.

35. A kit as in claim 34 where in component a) consists of a vial containing at least one random primer at least 4 nucleotides in length having at least one detectable species, and a vial containing at least one ~~NTP~~ ^{nucleotide triphosphate} having at least one binding species and optionally at least one ~~NTP~~ ^{nucleotide triphosphate}

36. A kit comprising

- a) a vial containing at least one random primer at least 4 nucleotides in length, having at least one binding species, and containing at least one NTP having at least one detectable species and optionally at least one ~~NTP~~ *nucleotide triphosphate*,
b) a vial containing at least one nucleic acid polymerase, and
c) a vial containing at least one solid phase.

37. A kit as in claim 36 where in component a) consists of a vial containing at least one random primer at least 4 nucleotides in length having at least one binding species, and a vial containing at least one NTP having at least one detectable species and optionally at least one NTP.

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